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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,411	10/16/2000	Norberto Festo	B-3992PCT618	7180

7590

06/25/2004

Richard P Berg  
Ladas & Parry  
Suite 2100  
5670 Wilshire Boulevard  
Los Angeles, CA 90036-5679

EXAMINER
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OH, TAYLOR V

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/673,411

**Applicant(s)**

FESTO, NORBERTO

**Examiner**

Taylor Victor Oh

**Art Unit**

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 June 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,4,13-15 and 18-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3,4,13,15,18-21,23,25-28,31,32,34,35,37,38 and 58 is/are allowed.
- 6) ☒ Claim(s) 14,22,24,29,30,33,36 and 39-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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The finality of the previous Office Action has been withdrawn and the application will be reopened in view of new grounds of rejection.

### ***Non-Final Rejection***

#### **The Status of Claims**

Claims 1, 3, 4, 13-15, 18-58 are pending.

Claims 14, 22, 24, 29, 30, 33, 36, and 39-57 have been rejected.

Claims 2, 5-12, 16-17 have been canceled.

Claims 1, 3-4, 13, 15, 18-21, 23, 25-28, 31-32, 34-35, 37-38, and 58 are allowable.

#### **Claim Objections**

Claims 14 and 44-57 are objected to because of the following informalities:

In claim 14, the term "a non-steroidal anti-inflammatory drugs " is recited. Both singular and plural forms are expressed at the same time in the term. This expression is grammatically incorrect. Therefore, an appropriate correction is required.

In claims 44-57, there are lots of spaces between the lists of the active ingredients.

The one section of claim 44 is exemplified as followed (see page 17, lines 3-23 in the claim section of the amendment on 6/1/04):

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Adrafinil, Adrenalone, Amidephrine,  
 Apraclonidine, Budralazine, Clonidine, Cyclopentamine, Detomidine,  
 Dimetofrine, Dipivefrin, Ephedrine, Epinephrine, Fenoxazoline,  
 Guanabenz, Guanfacine, Hydroxyamphetamine, Ibopamine, Indanazoline,  
 Isometheptene, Mephentermine, Metaraminol, Methoxamine  
 Hydrochloride, Methylhexanamine, Metizoline, Midodrine, Naphazoline,  
 Norepinephrine, Nordrenefrine, Octodrine, Octopamine, Oxymetazoline,  
 Phenylephrine Hydrochloride, Phenylpropanolamine Hydrochloride,  
 Phenylpropylmethylamine, Pholedrine, Propylhexedrine,  
 Pseudoephedrine, Rilmenidine, Synephrine, Tetrahydrozoline,  
 Tiamenidine, Tramazoline, Tuaminoheptane, Tymazoline, Tyramine  
 Xylometazoline, Albuterol, Bambuterol, Bitolterol,  
 Carbuterol, Clenbuterol, Clorprenaline, Denopamine, Dioxethedrine,  
 Dopexamine, Ephedrine, Epinephrine, Etafedrine, Ethylnorepinephrine,  
 Fenoterol, Formoterol, Hexoprenaline, Ibopamine, Isoetharine,  
 Isoproterenol, Mabuterol, Metaproterenol, Methoxyphenamine, Oxylfedrine,  
 Pirbuterol, Prenalterol, Procaterol, Protokylol, Reproterol, Rimiterol,  
 Ritodrine, Soterenol, Terbuterol, Xamoterol, Amosulalol, Arotinolol,  
 Dapiprazole, Doxazosin, Ergold Mesylates, Fenspiride, Indoramin, Labetalol,  
 Nicergoline, Prazosin, Terazosin, Tolazoline, Trimazosin, Yohimbine,  
 Acebutolol, Alprenolol, Amosulalol,

There is some space at the top , in the middle and at the bottom among the lists of the active ingredients. Furthermore, the space between the active ingredients is not proper. The same kind of improperness appears throughout claims 45-57. Therefore, an appropriate correction is required.

### Claim Rejections-35 USC 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14, 22, 24, 29, 30, 33, 36, and 39-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 14, the phrases “ the active ingredient comprises Troxerutine, Nimesulide, or a non-steroidal anti-inflammatory drugs” and “said non-steroidal anti-inflammatory drug comprises ” are recited. These expressions are vague and indefinite because the phrase “ the active ingredient comprises” would mean that there are other additional components besides the only one of them may be selected from the group of the following active ingredients: Troxerutine, Nimesulide, or non-steroidal anti-inflammatory drugs. Furthermore, “said non-steroidal anti-inflammatory drug comprises ” would mean that there are other additional components besides the only one of them may be selected from the group of the non-steroidal anti-inflammatory drugs. This same kind of indefiniteness regarding the phrase “ the active ingredient comprises” appears throughout claims 22, 24, 29, 30, 33, 36, 39-42, and 44-57. Therefore, an appropriate correction is required.

In claim 43, the phrase “ the phosphatidylcholine comprises ” is recited. The expression is vague and indefinite because the phrase “ the phosphatidylcholine comprises” would mean that there are other additional components besides the only phosphatidylcholine. Therefore, an appropriate correction is required.

Claim 57 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "derivatives thereof" is recited in the claim in pages 47 and 94 of Appendix K. The expression of the term "derivatives" is without further clarification by the specification. Therefore, an appropriate correction is required.

***Allowable Subject Matter***

Claims 1, 3-4, 13, 15, 18-21, 23, 25-28, 31-32, 34-35, 37-38, and 58 are allowable.

The close prior art to the current invention are Barz et al (EP 0390206) and Gross et al (U.S. 5,686,102).

Barz et al teaches stable emulsions containing perfluoropolyether from 0.01 to 99.9% by weight based on the total weight ( see page 6 , lines 14-30) with various molecular weights such as 870, 1320, and 6600 ( see page 7 , lines 24-25). Also, the applications for the emulsions are creams or pastes to prevent contact irritations and dermatitis or to protect the skin from sun ( see page 6 , lines 51-54).

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Furthermore, Gross et al teaches a pharmacological composition for topical administration involved in the use of perfluoropolyethers ( see col. 3 , line 19), phosphatidycholine in the range of from 30 to 99% ( see col. 2 , lines 40-41) , and dermatological active compounds containing antibiotics, anti-infectious agents, and anti-inflammatory drugs such as ibuprofen, piroxicam ( see col. 4 , lines 1-11). In addition, Gross et al has indicated that topical administration is formulated in such a way that pharmacological active compounds are delivered into a deep layer of the skin by means of a transdermal transport ( see col. 1 , lines 5-11).

However, the instant invention differs from the prior art in that none of them teaches the claimed compounds with or without the phosphatidylcholine.

Therefore, the claimed invention would not have been obvious to the person with an ordinary skill in the art.

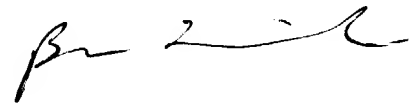
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached from 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Mckane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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6/22/54



BA K. TRINH  
PRIMARY EXAMINER  
GROUP 1200 1625